Managing Medications: A Pharmacy Perspective on Substance Use Disorder within an Interdisciplinary Primary Care Team

Brock Davis
PharmD, BC-ADM, MATS
Elizabeth Shinn
PharmD, BC-ADM

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

FQHC COMMUNITY HEALTH CENTER QUALITY
RECOGNIZED NCQA PATIENT-CENTERED MEDICAL HOME

Disclosures

Brock Davis has nothing to disclose.

Elizabeth Shinn has nothing to disclose.

Learning Objectives

1. Educate other individuals on the clinical pearls of each medication.
2. Illustrate and explain proper administration technique of each medication.
3. Identify and evaluate opportunities within individual community settings and practice sites to integrate pharmacy services within the MAT process.

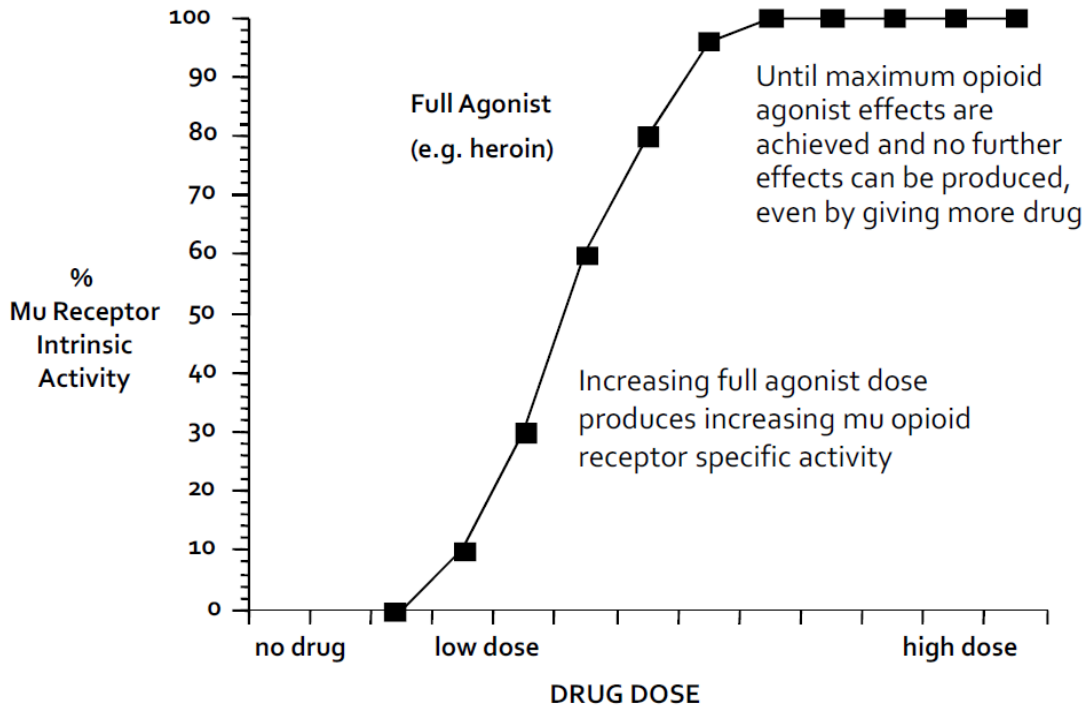
Opioid Pharmacology

Methadone

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Opioid Agonist

Full Agonist Activity Levels



HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Methadone

Mechanism of Action: **full opioid agonist that acts on opioid receptors in the brain**

Dosage Forms/Route of Administration: **tablets, oral solution, parenteral**

Pharmacokinetics: **80-90% oral bioavailability, onset of action 30-60 minutes, duration of action 24-36 hours for treatment of opioid use disorder**

Methadone. Waltham, Mass.: UpToDate. Retrieved from www.uptodate.com

Methadone

Dosing for Opioid Use Disorder (OUD): **20-40 mg for acute withdrawal; >80 mg for craving; observed intake daily vs "take home" (based on time in treatment and stability in program)**

Who May Prescribe: **highly regulated, limited to Opioid Treatment Programs (OTPs)**

Monitoring Parameters: **nursing assessment, individual/group counseling, random drug testing, psychiatric/medical services, drug-drug interactions**

Methadone

Benefits: **increases overall survival, increases retention in program, decreases illicit opioid use**

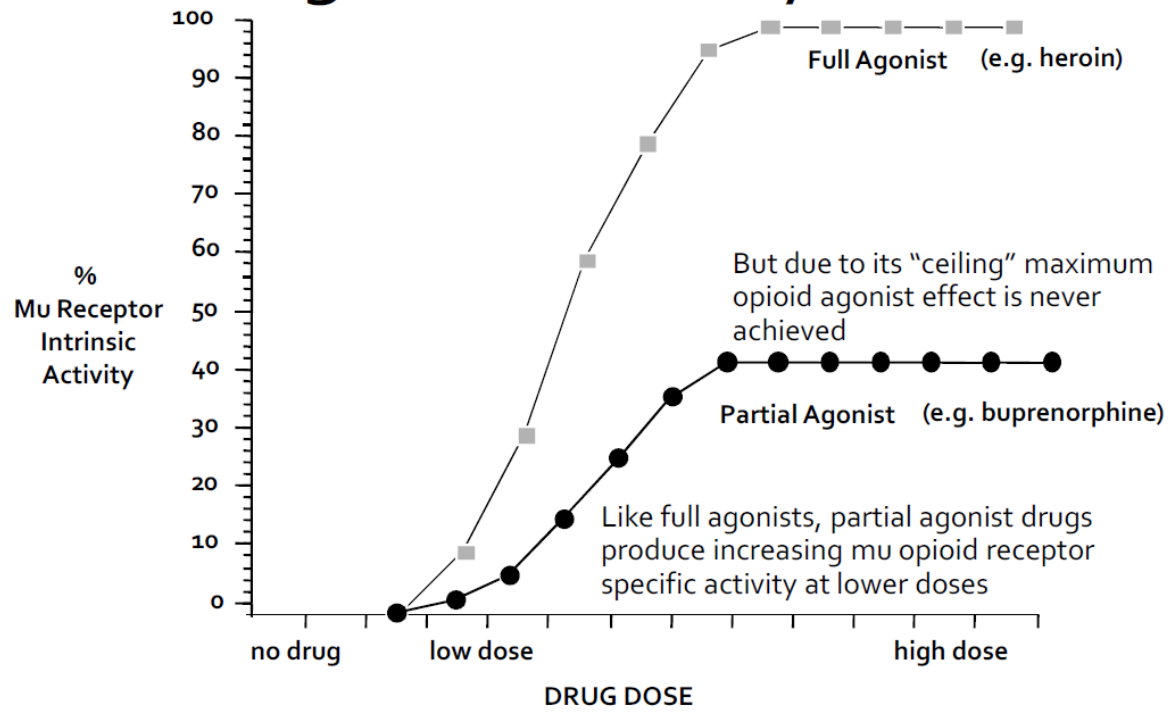
Limitations: **limited access, inconvenient, lack of privacy, stigma**

Clinical Use/Ideal Candidate: **patients participating in an outpatient opioid use treatment program**

Buprenorphine

Partial Opioid Agonist

Partial Agonist Activity Levels



HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Buprenorphine

Mechanism of Action: **partial opioid agonist that acts on opioid receptors in the brain; approved for moderate to severe OUD, may be used OFF LABEL for pain**

Dosage Forms/Route of Administration: **sublingual tablets, films, and IM; available as buprenorphine or in combination with naloxone; not time released, tablet and films may be split**

Buprenorphine. Waltham, Mass.: UpToDate. Retrieved from www.uptodate.com

Buprenorphine

Purpose of combination of buprenorphine with naloxone: if combination formulation is crush, dissolved, or injected, naloxone will block the opioid agonist effect of buprenorphine (see examples on next slide)

Medications Approved for the Treatment of Opioid Use Disorder

Suboxone sublingual tablets	Active Ingredient	
	Buprenorphine	**Naloxone**
	Is it active?	
Dissolved sublingually?	Yes	No
Swallowed whole?	Yes	No
Injected?	**Yes**	**Yes**

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Buprenorphine

Dosing for Opioid Use Disorder (OUD): **dosing varies patient-to-patient, can have split dosing; max 24 mg/day**

Who May Prescribe: **providers with the DATA 2000 waiver**

Monitoring Parameters: **liver function tests, pregnancy test, random drug tests, drug-drug interactions**

Buprenorphine

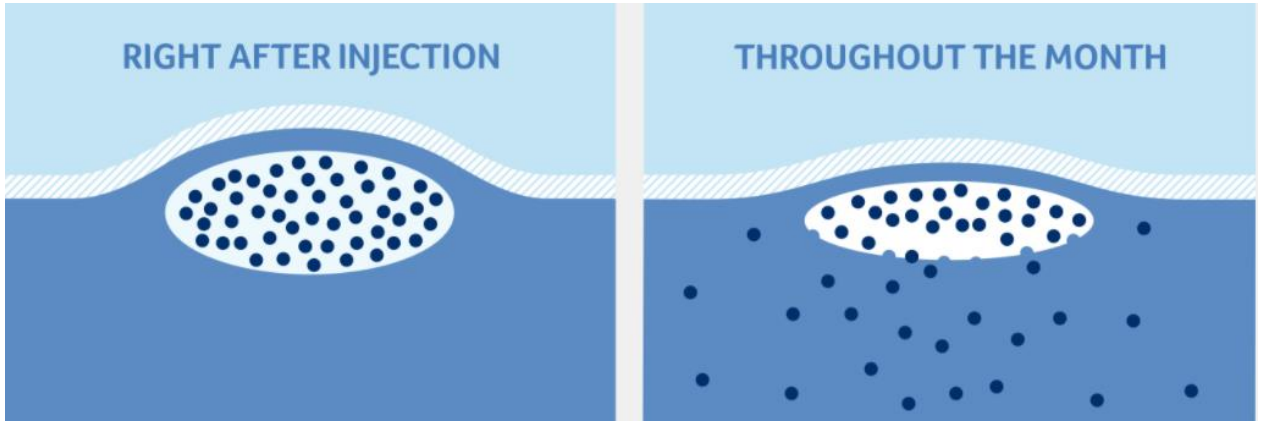
Benefits: **minimal overdose risk, studies show similar efficacy to methadone with outcomes of opioid use, retention in program, and decreased opioid craving, ease of dosing, may be used in pregnancy (mono)**

Limitations: **finding a waivered provider, stigma, side effects (nausea, constipation, sedation), CIII**

Clinical Use/Idea Candidate: **reduce cravings in patients with diagnosed opioid use disorder, patients with history of overdose, patients with chronic pain requiring opioid treatment**

Sublocade Injection

- Given as a subcutaneous injection in abdomen at 45 degrees
  - Rotate injection site
- Store in locked, secure refrigerator
- Bring to room temperature 15 minutes prior to injection
- Check color of liquid: range from clear to amber



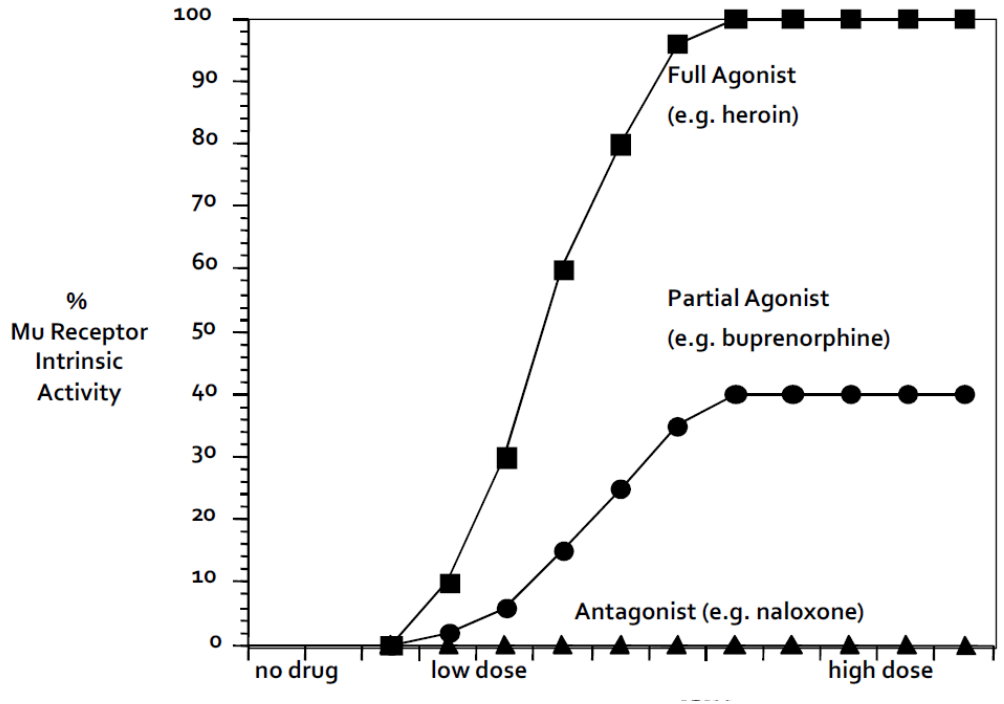
HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Naltrexone

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Opioid Antagonist

Opioid Agonists and Antagonists



Antagonist:
-occupies without activating
-is not reinforcing/rewarding
-blocks opioid agonists

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Naltrexone

Mechanism of Action: **full opioid antagonist that blocks opioid receptors without agonist effects; no tolerance or risk for physical withdrawal**

Dosage Forms/Route of Administration: **oral tablet, IM injection**

Who May Prescribe: **may be prescribed by any provider who is licensed to prescribe medications**

Naltrexone. Waltham, Mass.: UpToDate. Retrieved from www.uptodate.com

Naltrexone

Dosing for Opioid Use Disorder (OUD):

Oral formulation

- **25 mg/day initially, followed by 50 mg/day thereafter;**
  - **may use 100 mg every other day, or 150 mg every 3 days**

oral induction requires 5-7 days heroin and short-acting opioid free, 7-10 days buprenorphine or methadone free

Intramuscular

- **380 mg every 4 weeks**

***must be opioid free for minimum 7-10 days before IM treatment**

Naltrexone

Benefits: **provider does not need special training**

Limitations: **IM formulation costly, side effects (nausea, vomiting, diarrhea, headache, muscle/joint pain), must be opioid-free for several days before initiating therapy**

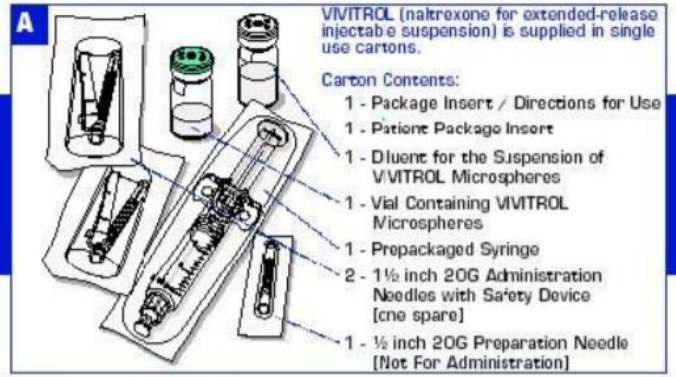
Clinical Use/Idea Candidate: **patients who are abstinent but at risk for relapse, patients with less severe form of opioid use disorder (short history of use or lower level of use), patients who failed prior treatment with agonist**

Vivitrol Injection Technique

Directions for Use:
To ensure proper dosing, it is important that you follow the preparation and administration instructions outlined in this document.

Product to be prepared and administered by a healthcare professional.
Do not substitute carton components.
Keep out of reach of children.
Prepare and administer the VIVITROL suspension using aseptic technique.

A



VIVITROL (naltrexone for extended-release injectable suspension) is supplied in single use cartons.

Carton Contents:

- 1 - Package Insert / Directions for Use
- 1 - Patient Package Insert
- 1 - Diluent for the Suspension of VIVITROL Microspheres
- 1 - Vial Containing VIVITROL Microspheres
- 1 - Prepackaged Syringe
- 2 - 1½ inch 20G Administration Needles with Safety Device [one spare]
- 1 - ½ inch 20G Preparation Needle [Not For Administration]

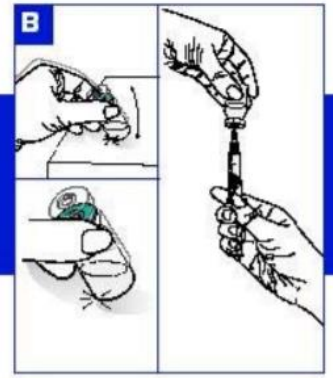
THE CARTON SHOULD NOT BE EXPOSED TO TEMPERATURES EXCEEDING 25 °C (77 °F).

VIVITROL must be suspended only in the diluent supplied in the carton, and must be administered with the needle supplied in the carton. Do not make any substitutions for components of the carton.

The entire carton should be stored in the refrigerator (2-8 °C, 36-46 °F). Unrefrigerated, VIVITROL Microspheres can be stored at temperatures not exceeding 25 °C (77 °F) for no more than 7 days prior to administration. Do not expose unrefrigerated product to temperatures above 25 °C (77 °F). VIVITROL should not be frozen.

Parenteral products should be visually inspected for particulate matter and discoloration prior to administration whenever solution and container permit.

B



1. Remove the carton from refrigeration. Prior to preparation, allow drug to reach room temperature (approximately 45 minutes).

2. To ease mixing, firmly tap the vial on a hard surface, ensuring the powder moves freely. (see Figure B)

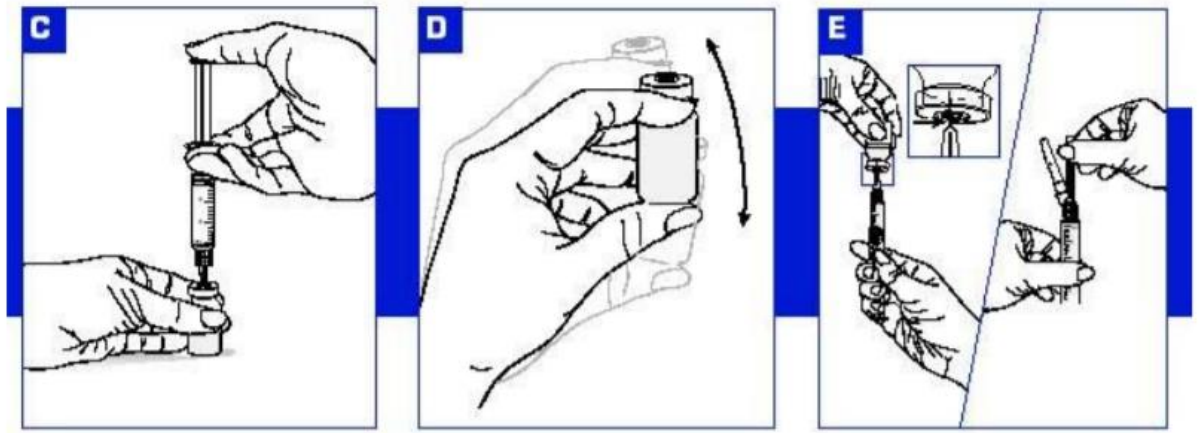
3. Remove flip-off caps from both vials. DO NOT USE IF FLIP-OFF CAPS ARE BROKEN OR MISSING.

4. Wipe the vial tops with an alcohol swab.

5. Place the ½ inch preparation needle on the syringe and withdraw 3.4 mL of the diluent from the diluent vial. Some diluent will remain in the diluent vial. (see Figure B)

Alkermes. Vivitrol (naltrexone) [package insert]. U.S. Food and Drug Administration. www.accessdata.fda.gov/drugsatfda_docs/label/2007/021897s003lbl.pdf

Vivitrol Injection Technique



Inject the 3.4 mL of diluent into the VIVITROL Microsphere vial. (see Figure C)

Mix the powder and diluent by **vigorously** shaking the vial for approximately 1 minute. (see Figure D) Ensure that the dose is thoroughly suspended prior to proceeding to Step E.

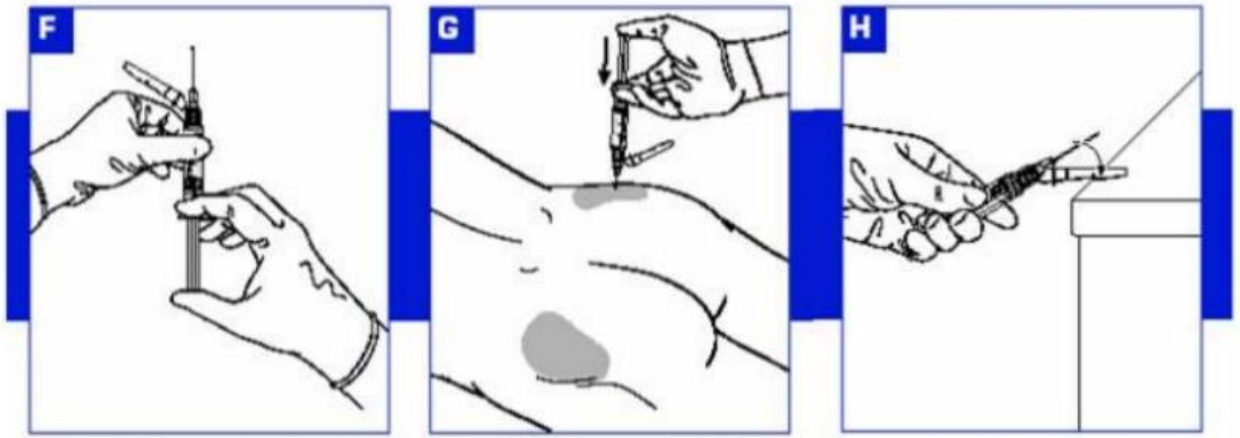
A PROPERLY MIXED SUSPENSION WILL BE MILKY WHITE, WILL NOT CONTAIN CLUMPS, AND WILL MOVE FREELY DOWN THE WALLS OF THE VIAL

1. Immediately after suspension, withdraw 4.2 mL of the suspension into the syringe using the same preparation needle.

2. Remove the preparation needle and replace with a 1½ inch administration needle for immediate use. (see Figure E)

Alkermes. Vivitrol (naltrexone) [package insert]. U.S. Food and Drug Administration. www.accessdata.fda.gov/drugsatfda_docs/label/2007/021897s003lbl.pdf

Vivitrol Injection Technique



Prior to injecting, tap the syringe to release any air bubbles, then push gently on the plunger until **4 mL** of the suspension remains in the syringe. (see Figure F)

THE SUSPENSION IS NOW READY FOR IMMEDIATE ADMINISTRATION.

1. Administer the suspension by deep intramuscular (IM) injection into a gluteal muscle, alternating buttocks per injection. Remember to aspirate for blood before injection. (see Figure G)

2. Inject the suspension in a smooth and continuous motion.

3. If blood aspirates or the needle clogs, do not inject. Change to the spare needle provided in the carton and administer into an adjacent site in the same gluteal region, again aspirating for blood before injection.

VIVITROL must NOT be given intravenously.

After the injection is administered, cover the needle by pressing the safety sheath against a hard surface using a one-handed motion away from self and others. (see Figure H)

Activation of the safety sheath may cause minimum splatter of fluid that may remain on the needle after injection.

DISPOSE OF USED AND UNUSED ITEMS IN PROPER WASTE CONTAINERS

Alkermes. Vivitrol (naltrexone) [package insert]. U.S. Food and Drug Administration. www.accessdata.fda.gov/drugsatfda_docs/label/2007/021897s003lbl.pdf

What next?

Provider consults with other members of healthcare team (BHC/psych, pharmacist, community health worker, etc)

- *Consider risk vs. benefit*
- *Cost*
- *Follow-up*
- *Goal of therapy*
- *Patient unique history and circumstances*

HealthLinc MAT Procedure

1) **MAT Assessment**
   a) *Appointment with DATA provider*
   b) *Appointment with Psych/BHC*
   c) *PA process initiation with pharmacist*
2) **MAT Induction Appointment**
3) **MAT Follow-up Appointment**

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Pharmacist Role

- *Determine medication selection from DATA provider*
- *Identify patient insurance*
- *Check insurance formulary*
- *Obtain necessary information if prior authorization (PA) is needed*

Supportive Medications

Ibuprofen - pain
Clonidine - anxiety
Imodium - diarrhea
Promethazine - nausea
Narcan – opioid overdose

Potential Information for PA

a) What medications has the patient tried/dates
b) Urine drug screen
c) Name of therapist
d) Pregnant?
e) Maximum dose?

In-Office Induction with Buprenorphine

1. Patient will pick-up initial 3-day rx of buprenorphine from pharmacy and bring to clinic (ie 10 tablets of 8-2 mg tablets)

2. COWS scale will be done to determine patient's level of withdrawal

COWS Score	Action
< 8	Reschedule or have patient wait
8 – 13	Initiate with 2mg buprenorphine
13+	Initiate with 4mg buprenorphine

3. Patient remain under observation for about an additional hour, and COWS scale reassessed

COWS Score	Action
13+	Administer second dose of 4 mg
6 – 13	Administer second dose of 2 mg
< 6	Patient education (II.d) and discharge

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

In-Office Induction with Buprenorphine cont.

4. Pharmacist educate patients how to assess withdrawal, when to take further doses as needed, and how to take medication properly

- ***Day 1: after leaving the office, may take an additional 2 mg if symptoms persist, max 8 mg on Day 1***
- ***Day 2: start with Day 1 dose, additional if needed, max 16 mg***
  ****Clinical pharmacist follow-up on Day 2 for check-in***
- ***Day 3: start with Day 2 dose, +/- 4 mg if needed based on symptoms***
- ***Day 4 and beyond: continue with Day 3 dose***
  ****adjustments made beyond this point done with consultation with provider and clinical pharmacist***

COWS (Clinical Opioid Withdrawal) Scale

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

CLINICAL OPIATE WITHDRAWAL SCALE (COWS)

For Buprenorphine/naloxone induction: Enter scores at time zero, 30 min after first dose, and at additional times that buprenorphine/naloxone is given over the induction period.

	TIME:	TIME:	TIME:
Resting Pulse Rate: (record beats per minute) *Measured after patient is sitting/lying for one minute.* 0 pulse rate 80 or below 1 pulse rate 81-100 2 pulse rate 101-120 4 pulse rate greater than 120			
Sweating: *Over past ½ hour not accounted for by room temperature or patient activity.* 0 no report of chills of flushing 1 one subjective report of chills or flushing 2 flushed or observable moistness on face 3 beads of sweat on brow or face 4 sweat streaming off face			
Restlessness: *Observation during assessment.* 0 able to sit still 1 report difficulty sitting still, but is able to do so 3 frequent shifting or extraneous movements of legs/arms 5 unable to sit still for more than a few seconds			
Pupil Size: 0 pupils pinned or normal size for room light 1 pupils possibly larger than normal for room light 2 pupils moderately dilated 5 pupils so dilated that only rim of the iris is visible			
Bone or Joint aches: *If patient was having pains previously, only the additional component attributed to opiate withdrawal is scored.* 0 not present 1 mild diffuse discomfort 2 patient reports severe diffuse aching of joints/muscles 4 patient is rubbing joints or muscles and is unable to sit still because of discomfort			
Runny nose or tearing: *Not accounted for by cold symptoms or allergies.* 0 not present 1 nasal stuffiness or unusually moist eyes 2 nose running or tearing 4 nose constantly running or tears streaming down cheeks			

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

GI Upset: *Over last ½ hour* 0 no GI symptoms 1 stomach cramps 2 nausea or loose stools 3 vomiting or diarrhea 5 multiple episodes of diarrhea or vomiting			
Tremor: *Observation of outstretched hands* 0 no tremor 1 tremor can be felt, but not observed 2 slight tremor observable 4 gross tremor or muscle twitching			
Yawning: *Observation during assessment* 0 no yawning 1 yawning once or twice during assessment 2 yawning three or more times during assessment 4 yawning several times/minute			
Anxiety or Irritability 0 none 1 patient reports increasing irritability or anxiousness 2 patient obviously irritable, anxious 4 patient so irritable or anxious that participation in the assessment is difficult			
Gooseflesh skin 0 skin is smooth 3 piloerection of skin can be felt or hairs standing up on arms 5 prominent piloerection			
Total Score			
Observers Initials			
Blood Pressure/Pulse			
Dose of Buprenorphine/naloxone Given			

Note: Give first dose when COWS score ≥ 8

SCORE:
5-12 = Mild
13-24 = Moderate
25-36 = moderately severe
More than 36 = severe withdrawal

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Pharmacist Follow-Up

- *Explain and provide patient with tracking sheet to track dosing and instructions*
- *Explain proper administration of sublingual formulations*
- *Instruct patient to call office if complications or concerns*
  - *Many patients have direct extension to call clinical pharmacist with dosing issues, PA's, etc.*

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Home Induction with Buprenorphine

1. *Patient will do induction from comfort of own home*
2. *When SOWS (subjective opioid withdrawal scale) score is at least 17, patient may take 4 mg of buprenorphine*
3. *After 1-3 hours, if still having withdrawal symptoms, may take additional 2 mg*
4. *After 6-12 hours, if continuing to have withdrawal symptoms, may take one more additional dose of 2 mg*

**During this time, may consult with clinical pharmacist and go over SOWS score*

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

SOWS Scale

Subjective Opiate Withdrawal Scale (SOWS)

Instructions: We want to know how you're feeling. In the column below today's date and time, use the scale to write in a number from 0-4 about how you feel about each symptom right now.

Scale: 0 = not at all 1 = a little 2 = moderately 3 = quite a bit 4 = extremely

DATE						
TIME						
	SYMPTOM	SCORE	SCORE	SCORE	SCORE	SCORE
1	I feel anxious					
2	I feel like yawning					
3	I am perspiring					
4	My eyes are tearing					
5	My nose is running					
6	I have goosebumps					
7	I am shaking					
8	I have hot flushes					
9	I have cold flushes					
10	My bones and muscles ache					
11	I feel restless					
12	I feel nauseous					
13	I feel like vomiting					
14	My muscles twitch					
15	I have stomach cramps					
16	I feel like using now					
TOTAL						

Mild Withdrawal = score of 1 – 10
Moderate withdrawal = 11 – 20
Severe withdrawal = 21 – 30

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

Utilizing Community Pharmacists

- Talk to local community pharmacists
  - Starting MAT program in clinic
  - Make sure medications are in stock
    - (tablets, films, Vivitrol injection)
    - "Comfort Kits"
  - Delivery option to clinic?
    - Helpful for in-office inductions

HealthLinc Map

Thank You!

Questions?

Brock Davis, PharmD, BC-ADM, MATS
Clinical Pharmacist – Mishawaka
bdavis@healthlincchc.org
574-307-7673 ext. 2610

Elizabeth Shinn, PharmD, BC-ADM
Clinical Pharmacist – Michigan City
eshinn@healthlincchc.org
219-872-6200 ext. 3777

HealthLinc
YOUR COMMUNITY HEALTH CENTER®

FQHC

HEALTHLINCCHC.ORG

EAST CHICAGO | KNOX | LA PORTE | MICHIGAN CITY | MISHAWAKA | SOUTH BEND | VALPARAISO